



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2013-N-1421]

Guidance for Industry on What You Need To Know About Establishment, Maintenance, and Availability of Records--Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "What You Need To Know About Establishment, Maintenance, and Availability of Records--Small Entity Compliance Guide" (SECG), which updates an earlier guidance of the same title. Previously, this guidance restated the legal requirements of FDA's maintenance and establishment of records regulation and served as that regulation's SECG.

Because the FDA Food Safety Modernization Act (FSMA) amended FDA's maintenance and establishment of records regulation, FDA issued an interim final rule (IFR) amending certain regulations to be consistent with the changes. Accordingly, FDA is revising this guidance to help any entity comply with FDA's maintenance and establishment of records requirements, including the amendments to these requirements made by the IFR as finalized. This guidance continues to serve as FDA's SECG.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Outreach and Information Center, Center for Food Safety and Applied Nutrition, Food and Drug

Administration (HFS-009), 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-

addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: William A. Correll, Jr., Office of Compliance, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1611.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled "What You Need To Know About Establishment, Maintenance, and Availability of Records--Small Entity Compliance Guide (SECG)." This guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The guidance represents our current thinking on the establishment, maintenance, and availability of records. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

FSMA (Pub. L. 111-353), among other things, amended FDA's records access under section 414(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In the Federal Register of February 23, 2012 (77 FR 10658), FDA issued an IFR that amended certain requirements on the availability of records in the regulation on the establishment and maintenance of records in 21 CFR Part 1, Subpart J to be consistent with amendments to the FD&C Act made by FSMA. This interim final rule was effective March 1, 2012.

Previously, this guidance restated the legal requirements of FDA's establishment and maintenance of records regulation at 21 CFR Part 1, Subpart J, implementing section 414 of the FD&C Act, as added by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188). This guidance also served as FDA's SECG for 21 CFR Part 1, Subpart J in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121). Because section 101 of FSMA amended section 414(a) of the FD&C Act, FDA issued an IFR amending certain requirements on the availability of records in 21 CFR Part 1, Subpart J. Elsewhere in this issue of the Federal Register, we are issuing a final rule adopting the IFR without changes. The final rule is effective upon publication. Accordingly, FDA is updating this SECG to help any entity comply with the requirements in 21 CFR Part 1, Subpart J, including the amendments to 21 CFR Part 1, Subpart J made by the IFR and adopted as final. This guidance continues to serve as FDA's SECG for 21 CFR Part 1, Subpart J.

The Regulatory Flexibility Act (5 U.S.C. 601-612) requires Agencies to determine whether a final rule will have a significant impact on small entities when an Agency issues a final rule "after being required...to publish a general notice of proposed rulemaking." Although FDA is not required to perform a regulatory flexibility analysis because, in accordance with 5 U.S.C. 553(b)(3)(B) and 21 CFR 10.40(e)(1), the Agency found for good cause that use of prior notice and comment procedures were contrary to the public interest; FDA has nonetheless examined the economic implications of the final rule in accordance with the Regulatory Flexibility Act and determined that the final rule will not have a significant economic impact on a substantial number of small entities. Similarly, because FDA is not required to perform a final regulatory flexibility analysis under 5 U.S.C 605(b) for the final rule, FDA is not required to issue an SECG to comply with section 212 of the Small Business Regulatory Enforcement

Fairness Act (Pub. L. 104-121); nevertheless, FDA has updated this SECG to state in plain language the requirements of 21 CFR Part 1, Subpart J, as amended by the final rule.

II. Paperwork Reduction Act of 1995

This guidance refers to information collection provisions found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). Except for the provision regarding access to records, the collections of information in 21 CFR Part 1, Subpart J, have been approved under OMB control number 0910-0560. With regard to access to records, we conclude that these information collection provisions are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or Agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an Agency against specific individuals or entities. The regulations in 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: April 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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